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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,657	11/29/2001	Charles Raymond Degenhardt	8375D	6277

27752 7590 11/20/2002

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/996,657

Applicant(s)

DEGENHARDT ET AL.

Examiner

RITA J. DESAI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-6,9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 4.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III in Paper No. 2 is acknowledged.

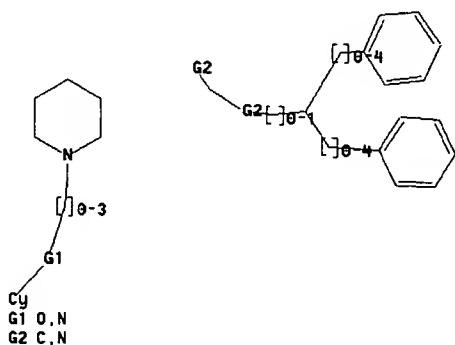
However the applicants were unable to elect a disclosed species for search purposes.

Hence applicants changed the election to group IV, with a disclosed species as the first appearing compound of column 2 on page 11.

Group IV is drawn to Claim 9 and 1,2, 5,11-16 in part, drawn to compounds, pharmaceutical compositions and methods of treating wherein D4 is CHR1, D5 is -OR6, R2 is as given in claim 6, R1 is a Hydrogen or a hydroxyl, x is 0 or 1, A4 is a six membered with one nitrogen, R6 is aromatic group, a substituted aromatic group, carbocyclic group, classified in class 546, 514, subclass 236, 326.

The traversal is on the ground(s) that the examiner has not shown that the groups are independent and distinct. This is not found persuasive because the applicants compounds do not have a common core.

When a preliminary search of the substituents with a variable linker was made it gave an incomplete search. See below.



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=> s 13

SAMPLE SEARCH INITIATED 12:08:04 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 54166 TO ITERATE

1.8% PROCESSED 1000 ITERATIONS 0 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.02

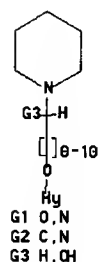
FULL FILE PROJECTIONS: ONLINE \*\*INCOMPLETE\*\*

BATCH \*\*INCOMPLETE\*\*

PROJECTED ITERATIONS: EXCEEDS 1000000

This incomplete search indicates that the core is not novel, and hence is not the applicants contribution over the prior art.

Even a search of the core for group III, gave numerous iterations as given below.



2.7% PROCESSED 1000 ITERATIONS 7 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*INCOMPLETE\*\*

BATCH \*\*INCOMPLETE\*\*

PROJECTED ITERATIONS: 725915 TO 748765

The requirement is still deemed proper and is therefore made FINAL.

This incomplete search indicates that the core is not novel, and hence is not the applicants contribution over the prior art.

This application is being examined to the extent of group IV as given above. 1-6, 9, 11-16.

#### ***Claim Objections***

Claim 12 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s) since these claims are also directed towards composition and hence are duplicates of claim 11 and 13.

Are applicants trying to claim a method of treating?

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a phenyl, naphthyl, alkyl, quinoline, pyridine, does not reasonably provide enablement for any and all carbocyclic, hydrocarbon substituted or unsubstituted group. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the invention commensurate in scope with these claims without any undue experimentation.

In re Wands , 858 F. 2d 731,737,8 USPQ@d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

The specification gives some preferred groups but does not give any guidance for other hydrocarbons and carbocyclic or aromatic compounds.

The art of treating diseases works in a lock and key mechanism and hence the predictability that any and all group will have the same effect is very very low. The specifications have a few examples and hence does not give any guidance for any and all the various groups.

Applicants can overcome this by limiting it to the groups specified in the specifications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3 and 6 , the phrase "about" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Applicants can overcome this rejection by inserting a definite range.

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Claim 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is a method of treating but does not provide the steps and process for doing so.

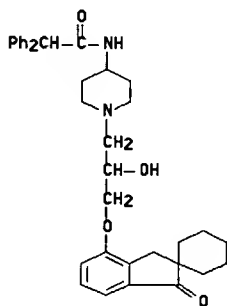
Applicant can overcome this by inserting an "effective amount of"

### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 3524955, FR 2567885, Berthold Richard et al.

The reference discloses the compounds of the invention. See



Spiro[cyclohexane-1,2'-(2H)]indene], benzeneacetamide.

Compound 56 reads on claim 1 compounds, wherein x is 0, D1 is NH, D2 is C=O, R2 is a biphenyl of the group as given in claim 6, R1 is hydrogen, or hydroxy, D4 is CHR1, t is 2, D5 is OR6, and R6 is a substituted hydrocarbon group, or a substituted aromatic group according to the definitions given in the specifications.

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***Conclusion***

The claims are hence not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "R. Desai", with a horizontal line drawn underneath it.

R.D.

November 14, 2002